

# FOOD AND DRUG ADMINISTRATION

Center for Tobacco Products (CTP)

## Tobacco Products Scientific Advisory Committee (TPSAC)

Gaithersburg Marriott Washingtonian Center  
9751 Washingtonian Boulevard, Rockville, MD 20878

July 15-16, 2010

## AGENDA

### July 15, 2010

8:30 Call to Order

Jonathan Samet, M.D.  
Chair, TPSAC

8:35 Conflict of Interest Statement

Cristi Stark, M.S.  
Acting Designated Federal Official  
FDA

8:40 Introduction of Committee Members

8:50 FDA Update on Upcoming Items and  
Other Committee Requests for Information  
on Menthol Cigarettes

Corinne Husten, M.D., M.P.H.  
CTP

9:00 Clarifying Questions

9:15 Industry Presentations – **Characterization of Menthol**

James E. Dillard III  
Senior Vice President- Regulatory Affairs  
Altria Client Services (on behalf of Philip Morris USA)

Jane Y. Lewis, Ph.D.  
Senior Vice President- Health and Analytical Sciences  
Altria Client Services (on behalf of Philip Morris USA)

Michael W. Ogden, Ph.D.  
Senior Director- Regulatory Oversight  
R.J. Reynolds Tobacco Company

William R. True, Ph.D.  
Senior Vice President- Research & Development  
Lorillard Tobacco Company

10:15 Break

10:30 Clarifying Questions

11:00 Industry Presentations – **Clinical Effects of Menthol**

Jane Y. Lewis, Ph.D.  
Senior Vice President- Health and Analytical Sciences  
Altria Client Services (on behalf of Philip Morris USA)

Michael W. Ogden, Ph.D.  
Senior Director- Regulatory Oversight  
R.J. Reynolds Tobacco Company

William R. True, Ph.D.  
Senior Vice President- Research & Development  
Lorillard Tobacco Company

12:00 Lunch

1:00 Clarifying Questions

1:30 Industry Presentations – **Biomarkers of Disease Risk**

Michael W. Ogden, Ph.D.  
Senior Director- Regulatory Oversight  
R.J. Reynolds Tobacco Company

Mohamadi A. Sarkar, Ph.D.  
Senior Principal Scientist- Health Sciences  
Altria Client Services (on behalf of Philip Morris USA)

William R. True, Ph.D.  
Senior Vice President- Research & Development  
Lorillard Tobacco Company

2:30 Break

2:45 Clarifying Questions

3:15 Industry Presentations – **Marketing Data**

Pascal A. Fernandez  
Vice President- Market Information & Consumer Research  
Altria Client Services (on behalf of Philip Morris USA)

Monica J. Graves  
Director- Marketing Operations  
Regulatory Oversight  
R.J. Reynolds Tobacco Company

Leonard H. Jones  
Director- Direct Marketing & Marketing Research  
Lorillard Tobacco Company

4:15 Clarifying Questions

5:00 Adjourn

**July 16, 2010**

8:00	Call to Order	Jonathan Samet, M.D. Chair, TPSAC
8:05	Conflict of Interest Statement	Cristi Stark, M.S. Acting Designated Federal Official FDA
8:15	Overview and Welcome Dr. Joshua Sharfstein, Principal Deputy Commissioner, FDA	
8:25	Industry Presentations – <b>Population Effects</b>	
	Geoffrey M. Curtin, Ph.D. Director- Regulatory Science Development/Engagement Regulatory Oversight R.J. Reynolds Tobacco Company	
	Jennifer L. Hunter Vice President- Corporate Affairs Altria Client Services (on behalf of Philip Morris USA)	
	William R. True, Ph.D. Senior Vice President- Research & Development Lorillard Tobacco Company	
9:25	Clarifying Questions	
9:55	Break	
10:10	<b>Open Public Hearing</b>	
11:10	Committee Discussion	
12:00	Lunch	
1:00	Committee Discussion	
2:30	Break	
2:45	Committee Discussion	
3:20	Closing remarks	David L. Ashley, Ph.D. CTP
3:30	Adjourn	